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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,875	04/05/2006	Jurgen Dorn	568-PDD-02-08-US-[57P]	7921

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EXAMINER	
WEBB, SARAH K	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
03/28/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,875	DORN ET AL.	
	Examiner	Art Unit	
	SARAH WEBB	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *27-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/28/2011 have been fully considered but they are not persuasive. Applicant argues that Keegan fails to disclose "a proximal end of the sleeve form-fitted over the primary shaft", as required by claim 1. The term "form-fitted" is a product-by-process recitation that is not given patentable weight, as the process by which the product is made is not germane to the issue of patentability of the device itself.

As explained in the previous office actions, the Office considers junction (9) and sleeve (4) to be integral components, as the junction (9) forms the proximal end of the sleeve (4) and they are fixed to one another to operate as a single component (see description of bonding by adhesive in paragraph 130). The sleeve (combination of 4 and 9) defines a proximal opening into which the primary shaft (2) is inserted and fixed so that the sleeve (4 and 9) and primary shaft (2) are not relatively moveable. The manner in which the sleeve is fixed over the shaft is irrelevant to the issue of patentability of the structures of the claimed invention. The Keegan device provides all the structures required by the claims and performs the functions as claimed.

Applicant argues that the manner in which the sleeve of the instant invention is "form-fitted" over the shaft provides the advantage of avoiding "issues" with withdrawal, but fails to specify how this is accomplished. Applicant argues that the separate components (4 and 9) of Keegan may have edges that catch on a guiding catheter during withdrawal, but Applicant had previously pointed out that Keegan discloses the

purpose of the junction (9) is to provide a smooth transition from the sheath (4) profile to the shaft (2) (see page 10). As illustrated clearly in Figure 19a, the junction (9) has an outer diameter that is flush with the outer diameter of the sleeve (4) so that no edges are present. Applicant's arguments fail to distinguish a structural difference between the claimed sleeve and the Keegan device, so the previous rejection has been maintained.

Applicant argues the disadvantages of two pieces bonded by adhesive as compared to a single piece, but this fails to distinguish over the structure disclosed by Keegan. Additionally, it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893).

Applicant argues that one of ordinary skill in the art would have been led away from extending the guide tube (101) proximally to overlap a length of the primary shaft (2), because it would have increased the diameter of the catheter. This is not found persuasive, because Keegan teaches that the length of the guidewire tubular means (101) of the Figure 19a embodiment can be extended rearward (paragraph 202). Since this modification would require a mere change in size or location of a component, this modification is considered to within an ordinary level of skill in the art. Additionally, the modification would have merely involved the combination of known configurations of the Keegan components according to known methods to obtain the predictable result of attaching both the primary shaft and guide tube to the sleeve (4 and 9). Therefore, the prior rejection is proper and has been maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-9, 11, 12, 15-20, 24-26, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent App. Pub. No. 2003/0109886 (Keegan et al.).

Referring to the embodiment of Keegan in Figure 19a, a surgical delivery device is disclosed that includes a primary shaft (2) attached to a distal zone that is advanced over a guide wire (3). A guidewire tubular means (101) lies in the distal zone to one side of the primary shaft (2). A proximal length of the guidewire tubular means (101) overlaps a distal length of the primary shaft (2). A sleeve (4 and 9; the proximal component 9 is considered to be an integral part of the sleeve 4) surrounds the primary shaft (2), the guide wire tubular means (101), and a surgical element (7) positioned at distal portion of the guidewire tubular means (101). The term "form-fitted" is a product-by-process recitation that is not given patentable weight, as the process by which the product is made is not germane to the issue of patentability of the device itself. The proximal guidewire exit port (11) is proximal to the proximal opening of the guidewire tubular means (101).

In this embodiment, Keegan fails to configure the guidewire tubular means (101) and the primary shaft to overlap in length, but Keegan illustrates this arrangement in another embodiment shown in Figure 18. Additionally, Keegan states that the length of

the guidewire tubular means (101) of the Figure 19a embodiment can be extended rearward (paragraph 202). Since this modification would require a mere change in size or location of a component, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure Figure 19a embodiment so that the primary shaft (2) overlaps a length of the guidewire tubular means (101). This modification would have merely involved the combination of known configurations of elements according to known methods to obtain the predictable result of attaching both the primary shaft and guide tube to the sleeve (4 and 9).

Regarding claims 2-4, Keegan discloses a moveable inner shaft (3) received in the primary shaft tube. The inner shaft is configured as a "pusher", as it is *capable of* maintaining the position of stent (7). Meeting all the structural requirements, the prior art is not necessarily required to disclose the function *"maintain the position of said surgical element...."*

Regarding claims 5 and 6, Keegan discloses the delivery of a self-expanding stent (paragraph 118).

Regarding claims 7-9, Keegan teaches that a sleeve can be reinforced by braided filamentary material within the wall thickness of the sleeve (paragraph 119). It would have been an obvious matter of design choice to extend the reinforcement along the sleeve at a length that provides sufficient support to the sleeve.

Regarding claim 11, the claimed phrase "form-fitted by the application of heat and radially inward pressure" is being treated as a product by process limitation. As set

forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference.

Regarding claims 12 and 15, the proximal end of the sleeve meets the broad requirement of a "push zone", since it is capable of receiving a compressive force from the primary shaft. This "push zone" can be found immediately distal of the distal end of the primary shaft.

Regarding claims 16 and 17, the tubular structure of the guidewire tubular means (101) is considered to meet the broad requirements of a "guider tube" and a "guide hose", since no further structural limitations are recited for these features.

Regarding claim 18, Keegan teaches that a guidewire guider tube should be flared at the distal end in order to guide the guidewire into the lumen (see paragraph 149 and Figures 3c-e, 28-30). In light of this teaching, it would have been obvious to one of ordinary skill in the art to incorporate this feature into the distal end of the guidewire tubular means of the embodiment of Figure 19a.

Regarding claim 19: Although Keegan does not configure the inner shaft (2) of the Figure 19a embodiment to extend distally beyond the distal end of the guider hose (101), Keegan does disclose other embodiments where the inner shaft (2) extends distally of the guidewire tubular means. Such a configuration is shown in Figure 3, where the inner shaft (3) extends beyond guidewire guide lumen (between 9 and 11). It would have been obvious to one of ordinary skill in the art to configure the components

of the Figure 19a embodiment so that the inner shaft (2) extends beyond the distal end of guidewire hose (101), as this modification would require a mere change in size of a component and/or change in relative positions of components.

Regarding claim 20, the inner shaft (3) carries a pusher (34) which defines a lumen aligned with the guidewire lumen defined by guider hose (101). As shown in the cross section of Figure 19b, the pusher (34) extends beyond the guider hose (101).

Regarding claim 24, the position of the pusher (6) relative to the sleeve may be adjusted by axial movement provided to the annular pusher through its connection to the inner shaft (Fig. 26).

Regarding claim 25, the inner shaft (3) comprises a distal portion of solid cross-section (131) and a proximal tube portion (130), the tubular portion extending within the primary tube shaft and distally therefrom, to said connector, or to a point proximal of said connector (Fig. 26). Regarding claim 26, the inner shaft exhibits an unbroken metal strand as far as the annular pusher (Fig. 26).

Regarding claim 44, Keegan states that the guidewire tubular means (101) can be mounted to the primary shaft (par 203). "Welded" is a product by process limitation that is not given patentable weight, since the method by which a product is made is not germane to the issue of patentability of the structure itself. See MPEP 2113.

3. Claims 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. in view of US Patent App. Pub. No. 2008/026506 (Griffin et al.).

Keegan fails to configure the carrier tube/ pusher (34) so that it includes both an annular pusher and a carrier tube that extends distally from the annular pusher. Griffin discloses a similar type of rapid exchange device with essentially the same components as the Keegan device. In one embodiment shown in Figures 9a-b, a carrier tube/ pusher (9) is attached to the distal end of inner shaft (14) similar to the arrangement of Keegan. Griffin teaches an alternate arrangement that includes an annular pusher (61) connected to the distal end of the inner shaft (14) and a carrier tube (9) attached to the annular pusher (61) and extending distally and proximally from therefrom. It would have been obvious to one of ordinary skill in the art at the time the invention was made to from the carrier tube/ pusher element of the Keegan assembly so that it includes both an annular pusher and carrier tube, as taught by Griffin, as this modification merely involves a simple substitution of one known configuration for another to obtain predictable results.

Regarding claim 22, Keegan teaches that the carrier tube (5) can include a radiopaque marker (13) band at or near its distal end (paragraph 128; Fig. 3E).

Regarding claim 23, Keegan and Griffin fail to disclose that the proximal end of the carrier tube can be tapered outwardly towards the luminal wall of the sleeve. Keegan et al. disclose the funnel portion (12), which tapers outwardly toward the wall of the sleeve, assists in guiding the guidewire into the narrower guidewire lumen (paragraph 133). In light of this teaching, it would have been obvious to modify the carrier tube to also include a proximal portion which tapers outwardly towards the luminal wall of the sleeve in order to assist in guiding the guidewire into the carrier tube

so that the guidewire can easily be inserted through the proximal guidewire port if desired.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (US 2003/0109886) in view of Betelia et al. (US 6,945,989).

Keegan fails to disclose the distal end of the sleeve (4) is tapered inwardly to provide the device, at least prior to its arrival at the site of surgery, with a more or less atraumatic tip. Betelia et al. disclose stent delivery catheter for deploying a self expanding stent, wherein the stent delivery catheter comprises an outer sheath having a distal tip (18) which is tapered inwardly to provide an atraumatic tip (Fig 1 B; col. 5, ln. 65 - col. 6, ln. 9). Betelia et al. discloses the tapered outer sheath is advantageous over a conical or tapered nosepiece on the inner shaft, such as the nosepiece disclosed by Keegan et al, because the nosepieces risk catching on the wall of the blood vessel and/or dislodging embolic material (col. 2, ln. 4-22). Therefore, it would have been obvious to one of ordinary skill in the art to modify the sleeve of the Keegan device so that it is inwardly tapered at the distal end, as taught by Betelia, in order to facilitate advancement of the sheath with minimal risk of dislodging embolic material or causing injury to the vessel.

5. Claim 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (US 2003/0109886) in view of Roberts et al. (US 5,603,698).

Keegan fails to disclose that the push zone corresponds to an annulus, defined by a reduced outside diameter of the sleeve relative to its diameter immediately proximal of said push zone and reduced inside diameter relative to its inside diameter immediately proximal of said push zone. Roberts et al. disclose a self expanding stent delivery catheter having a sheath (20) with a reduced diameter portion (24; Fig. 1). Roberts et al. discloses that providing an outer sheath having diameters which conform closely to the diameter of the inner components enhances flexibility and reduces kinking for easier navigation through vessels (col. 5, ln. 14-44). It would have been obvious to one of ordinary skill in the art to decrease the inner and outer diameters of the sleeve of Keegan in the region distal the primary shaft, as taught by Roberts, in order to enhance flexibility and reduce kinking.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH WEBB whose telephone number is (571) 272-5749. The examiner can normally be reached on 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. W./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
03/23/11